

FORMAL ENTRY

CRAWFORD MAUNU PLLC  
Attorneys at Law  
1270 Northland Drive, Suite 390  
St. Paul, Minnesota 55120  
651-686-6633 • fax 651-686-7111

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GROUP 3700

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DATE:	June 12, 2003	SER. NO.:	10/041,911
ATTN:	Examiner Foreman	FROM:	Mark Hollingsworth
FAX NO.:	(703) 872-9302	DOCKET NO.	GUID.038US01
PHONE NO.:			
NO. OF PAGES (w/ cover sheet):	1 of 5	SUBJECT:	<u>Response to Restriction</u> <u>Requirement with</u> <u>Traverse</u>

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PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MANNING et al.	Examiner:	Foreman, J.
Serial No.:	10/041,911	Group Art Unit:	3736
Filed:	January 7, 2002	Docket No.:	GUID.038US01 (01-105)
Title:	STEERABLE GUIDE CATHETER WITH PRE-SHAPED ROTATABLE SHAFT		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence and the papers, as described hereinabove, are being transmitted via facsimile-Formal Entry, to the attention of the Examiner and the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 12, 2003.

Facsimile No.: (703) 872-9302

By: Kelly S. Waltigney

Kelly S. Waltigney

**RESPONSE TO RESTRICTION/ELECTION OF SPECIES REQUIREMENT****MAIL STOP NONFEE AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Non-Final Office Action dated May 12, 2003 in which a restriction requirement and election of species were made, the claims of Group I (1-15) are hereby elected with regard to the restriction requirement as between the Group I and II claims. As such, please cancel the claims of Group II (16-23) without prejudice for further prosecution in a related patent application. Applicant, however, traverses the Examiner's requirement for election of species.

In compliance with 35 U.S.C. § 121, Applicant hereby elects, with traverse, the claims readable on Embodiment 1 (Figs. 1-3A) identified by the Examiner as one of five purported distinct species. Commensurate with the disclosed aspects of the Embodiment 1, Applicant believes claims 1, 2, 9, 10-12, and 14 are readable on Embodiment 1.

Having complied with 35 U.S.C. § 121, Applicant respectfully asserts that the Examiner is overzealously and inappropriately applying the provisions of 35 U.S.C. § 121

with regard to the identification of five purported species and three purported sub-species in the disclosure. Nearly all of the figures, for example, in Applicant's disclosure have been identified by the Examiner as depicting distinct species within the context of 35 U.S.C. § 121.

In order for claims to be restricted to different species, such claims must be mutually exclusive (MPEP § 806.04(f)). Claims can be restricted to different species only where one claim recites limitations which, under the disclosure, are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first.

Applicant respectfully asserts that the Examiner's identification of species and sub-species in the Office Action (Embodiments 1-5 and sub-species associated with claims 13-15) is in error and does not comply with the requirements of MPEP § 806.04(f). For example, claim 6 can read on identified Embodiment 4 (Fig. 7), and claim 5 can read on identified Embodiment 5 (Fig. 8). Claim 6 recites limitations of an electrode on a distal end of a sheath and an associated electrical conductor disposed within the sheath and coupled to the electrode. Under the disclosure, these limitations recited in claim 6 of Embodiment 4 (i.e., a first species) are also found in Embodiment 5 (i.e., a second species).

Further, claim 5, which reads on Embodiment 5 (i.e., the second species), recites limitations of an electrode on a distal end of a sheath and an associated electrical conductor disposed within the sheath and coupled to the electrode. Under the disclosure, claim 5 recites essentially the same limitations disclosed for Embodiment 4 (i.e., the first species).

Applicant's disclosure, at page 13, line 24 through page 14, line 5 (emphasis added), makes clear that the mutually exclusive requirement of MPEP § 806.04(f) is not met for Embodiments 4 and 5 identified by the Examiner:

Another useful configuration of a guide catheter according to the present invention includes attaching electrodes to a distal end of the guide catheter. Figure 7 shows electrodes 17 mounted on the distal end of the outer sheath 2. The electrodes 17 are typically flush mounted, and are connected to at least one conductor 18 that is disposed between the distal and proximal ends of the inner sheath 1.

Figure 8 shows electrodes 19 mounted on the inner sheath 1 in a similar fashion as the electrodes 17 on the outer

sheath 2. The electrodes 19 are connected to at least one conductor 20 that is disposed within the inner sheath 1. It is understood the electrodes may be disposed on both the inner and outer sheaths 1, 2 in certain configurations.

The mutually exclusive requirement of MPEP § 806.04(f) is also not met for identified Embodiments 3 (Fig. 6) and 4. Claim 8 can read on Embodiment 3, and claim 7 can read on Embodiment 4 (Fig. 7). Both claims 7 and 8 recite an occlusion device disposed at a distal end of the sheath. Claim 7 recites the occlusion device limitation which, under the disclosure, is found in the species of Embodiment 4 and also in the species of Embodiment 3. Claim 8 recites the occlusion device limitation found in both Embodiments 3 and 4. Accordingly, the mutually exclusive requirement of MPEP § 806.04(f) is not met, as indicated in Applicant's disclosure at page 4, lines 7-9 (emphasis added):

The guide catheter may also include an occlusion device connected to the distal end of the inner sheath. An occlusion device may also be connected to the pre-shaped distal end of the outer sheath.

With regard to identified Embodiments 1 (Figs. 1-3A) and 2 (Fig. 5), the mutually exclusive requirement of MPEP § 806.04(f) is not met. Claims 3 and 4 can read on Embodiment 2, and claim 1, in addition to other claims, can read on Embodiment 1. Applicant's disclosure does not support an interpretation that the pres-stress line limitations of claims 3 and 4 of Embodiment 2 are disclosed only for the species of Embodiment 2, as is indicated at page 3, lines 23-28:

In one configuration, the steering mechanism includes a steering handle pivotably connected to the guide handle. In another aspect, the outer sheath may further include at least one longitudinally displaced pre-stress line extending from the proximal end to the distal tip of the outer sheath. Similarly, the inner sheath may further include at least one longitudinally displaced pre-stress line extending from a proximal end to a distal tip of the inner sheath.

Applicant respectfully asserts that the sub-species election requirement with regard to claims 13-15 is in error and necessitates withdrawal. The mutually exclusive requirement of MPEP § 806.04(f) is not met, as indicated by Applicant's disclosure at page 4, line 27 through page 5, line 2:

The steering tendon may be disposed on an outer surface of the outer sheath. Alternatively, the steering tendon may be disposed within the open lumen of the outer sheath. In yet another configuration, the outer sheath may further include a second lumen, and the steering tendon is disposed within the second lumen.

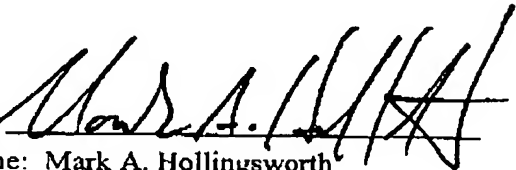
In the above-made arguments, Applicant is contesting the propriety of the Examiner's election of species restriction requirement. Applicant, however, is not traversing on the ground that the "species" identified by the Examiner are not patentably distinct, but rather is asserting that the basis for requiring election between species is not supported.

Applicant respectfully reminds the Examiner that, upon allowance of generic claim 1, Applicant is entitled to consideration of claims to additional species, including those identified by the Examiner, pursuant to 37 CFR 1.141.

Applicant respectfully requests that the Examiner reconsider the appropriateness of the 5-way species election requirement and 3-way sub-species election requirement. Applicant further requests that the Examiner seriously consider the undue burden and expense that would be borne by Applicant should the requirement be maintained. Reconsideration and withdrawal of the restriction requirement as to the election of species are, therefore, respectfully requested.

If the Examiner has any questions or comments, a telephone call to the number indicated below is invited.

CRAWFORD MAUNU PLLC  
1270 Northland Drive, Suite 390  
St. Paul, MN 55120  
(651) 686-6633 x104

By:   
Name: Mark A. Hollingsworth  
Reg. No.: 38,491